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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

REF: Docket No. 01N-0275
21 CFR 1020 Proposed Rule

Dear Sir:

The Illinois Department of Nuclear Safety hereby submits its comments on the above-identified rule, which proposes to revise standards for diagnostic x-ray equipment. This agency regulates the use of radiation producing machines in Illinois, and is particularly interested in the Food and Drug Administration's (FDA) changes to the manufacturing standards for such equipment. Our comments on the proposed rule follow:

Information to be Provided to Users (Sec. 1020.30(h))

We are supportive of FDA's requirement that manufacturers provide additional, detailed information for those fluoroscopic systems provided with a variety of special modes of operation and methods of recording fluoroscopic images. We too recognize that operators of these systems often have little knowledge as to what each mode was specifically designed for, which can result in an inappropriate application of the mode by the user. However, we believe that FDA should require manufacturers to provide data on the entrance air kerma rate for any fluoroscopic system, and for each of the various modes of operation. Although FDA had originally considered this requirement for multiple mode units, it was rejected as impractical, due to the large number of possible combinations and modes of operation available. Instead FDA is proposing an amendment to require a device that will display the air kerma and the cumulative air kerma, which will deviate by no more than +/- 25 percent from the actual values. If this is the best accuracy we can accomplish at this time, a lower cost alternative approach may be advisable.

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If FDA requires that additional information be provided, to include air kerma rates during various modes of operation, the operator would be able to use this information, with data collected during the procedure (cumulative fluoroscopic time), to determine the approximate dose to the patient. The accuracy of this method may be no worse than that of a device with a +/- 25 percent accuracy, and far less expensive for the user. In either case, we believe the value of any additional dose-monitoring device is significant only for interventional applications.

Change in the Requirements for Fluoroscopic X-ray Field Limitation (Sec. 1020.32(b)

We are opposed to FDA's expressed intent to promote the incorporation of continuously adjustable, circular collimators into all types of fluoroscopic x-ray systems with circular image receptors. Our inspection experience reveals that most of these units are very well collimated, with only a handful actually cited, and then quickly corrected, for exceeding the present beam limitation requirement. As such, when examining FDA's geometrical efficiency tables, one should take into account that these worse-case collimation scenarios are rarely exceeded. As such, this requirement will be expensive initially, costly for the user to maintain, and resultant dose saving potential much less than anticipated.

FDA also acknowledges that the new proposed collimation requirement could be met through the use of less complex (expensive), currently available, rectangular collimation and under-framing. Due to the cost differential, FDA should anticipate that this would probably be how most units are installed. As such, and as is currently the case, one year after the unit is installed, FDA will no longer be able to enforce its new collimation requirement on the user, and it will be left to the various state regulatory programs. Many of the states may not have, or be willing to change their rule to conform to FDA's. As such, the old state rule will apply, and the previously under-framed fluoroscopic beam will have now been enlarged to fill the input phosphor. FDA's well-intentioned effort in this area may only result in widespread avoidance.

We also question the benefit of the more restrictive collimation requirement for any extremity-only fluoroscopy device.

Entrance Air Kerma Rates and Rates at the Fluoroscopic Image Receptor

FDA specifically requested comments on the exemption from air kerma rate restrictions. We believe that any exemption to the limit of 180 mGy/min (vice 20 R/min) is inappropriate and unnecessary, particularly with the ability to add filtration to the beam.

Unnecessary radiation exposure often occurs on multiple-mode fluoroscopic systems because they have not been calibrated or optimized for each of the particular modes utilized. One output setting, usually with the highest dose, is often used. As such, we would be supportive of any effort to ensure optimum system performance. However, instead of considering additional limits on the entrance air kerma rate at the input surface of the image receptor, FDA should require manufacturers to specify typical target values for these rates in order to ensure optimal performance at the different imaging modes. This additional information would allow the user, medical physicist, or bio-medical engineer to easily determine if the unit is operating at its optimal setting.

Display of Fluoroscopic Irradiation Time, Air Kerma Rate, and Cumulative Air Kerma (Sec. 1020(h) and Proposed (k)

The proposed regulation will require a display of air kerma rate and cumulative air kerma. This information will obviously be of benefit to interventional applications, and to a lesser extent for routine fluoroscopy, but only if, as FDA notes, the devices to do so are commercially available, relatively inexpensive, and easy to maintain. However, we believe this requirement will be unnecessary and costly for users of small extremity-only fluoroscopy devices, since they have a relatively low radiation output.

We are also very supportive of FDA's proposal to change the current timer requirements, and believe it is sufficient that the cumulative time be displayed at the control console.

"Last Image Hold" Feature on Fluoroscopic Systems (Propose Sec. 1020.32(j))

We are supportive of a requirement that most fluoroscopic x-ray systems be provided with a means to continuously display the last image acquired prior to termination of exposure. However, we question whether it is really necessary for users of the small extremity-only fluoroscopy devices with relatively low radiation output. Would the additional cost of this device for these type units be justifiable?

Closing Remarks

Several of the new requirements are designed to provide additional information to the fluoroscopist, or improve technical aspects of the x-ray system, including beam quality and collimation. The purpose of these new requirements is to provide an additional margin of safety, in order to avoid radiation injury to patients. However, FDA notes in its Risk Assessment Section a statement adopted from the CIRRPC Science Panel Report that at this time, studies of human populations exposed to low doses of radiation are inadequate to demonstrate the actual level of risk. The report also notes the scientific

uncertainty about cancer risks in the low-dose region, and that the possibility of no cancer risk cannot be excluded. Since the risk of radiation injury is primarily related to interventional procedures, many of the proposed regulations may have little benefit/risk value for fluoroscopic devices that are used for routine applications. As the regulations are certain to add cost to the manufacture of x-ray equipment, perhaps the FDA should instead focus its efforts on those x-ray machines manufactured for interventional use.

We appreciate the opportunity to comment on this proposed rule, and commend the FDA for their efforts to update their regulations to adapt to emerging technologies. Questions regarding these comments should be directed to Paul H. Brown of our Division of Electronic Products at 217/785-9978.

Sincerely,

Gary N. Wright
Director

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